REMARKS

Reconsideration of this application is respectfully requested. Claims 20-38 are pending and at issue.

Obviousness-Type Double Patenting Rejection

Claims 20-38 have been provisionally rejected for obviousness-type double patenting over claims 1-8 of co-pending U.S. Patent Application No. 10/984,536. Applicants respectfully request that this rejection be held in abeyance because the application containing the conflicting claims has not been allowed and has not issued as a patent.

In the September 6, 2006 Office Action, the Examiner states that "he is perplexed by Applicant's interpretation of MPEP 804, especially since this application was never deemed allowable." *See* page 3 of the Office Action. For the purpose of clarifying the record, Applicants respectfully submit that Applicants' argument alluded to by the Examiner was based on the assumption that the remaining rejections would be withdrawn in view of the arguments provided in the prior response.

Obviousness Rejection

Claims 20-38 have been rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,943,590 ("Boegesoe"), in view of U.S. Patent No. 5,789,449 ("Norden"), the Merck Manual (16th ed., 1992, p. 1791), and Applicants' alleged admission of the prior art. The Examiner cites (i) Boegesoe for its teaching of escitalopram as a selective serotonin reuptake inhibitor ("SSRI"), (ii) Norden as teaching a method of treating premenstrual syndrome (PMS) using a SSRI, and (iii) the Merck Manual as teaching that depression is a symptom of PMS. The Examiner relies on the present specification for its disclosure that clinical studies of depression and anxiety disorders indicate that the rate of resistance or non-response to SSRIs is substantial. According to the Examiner, it would have been obvious for one of ordinary skill in the art to

treat PMS with escitalopram because depression associated with PMS can be treated with escitalopram.

Applicants traverse this rejection and respectfully request reconsideration.

Claims 20-38 are not obvious over Boegesoe because, *inter alia*, the cited references would not have motivated one of ordinary skill in the art to administer escitalopram for the treatment of PMS in patients who have failed to respond to treatment with an initial, non-escitalopram SSRI, as called for in the pending claims.

The claimed patient population specifically includes certain treatment-resistant patients suffering from PMS. By definition, administration of an SSRI (other than escitalopram) has been shown to be ineffective in treating PMS in these patients. Given the failure of a first SSRI to produce an effective response in these patients, one of ordinary skill in the art would not have reasonably expected the patients to be responsive to another member of the same drug class. In other words, one of ordinary skill would have had no reasonable expectation that these same patients could be effectively treated with another SSRI because they have already demonstrated resistance to treatment with an SSRI. In fact, any reasonable expectation of success associated with SSRIs would be necessarily diminished in this population.

There are several well known treatment options available for patients with PMS, including psychotherapy, stress reduction, diuretics, pain relievers, diet modification, and exercise. Given this wide range of options, one of ordinary skill in the art would not have been motivated to use another SSRI, such as escitalopram, to treat patients with PMS after therapy with a first SSRI already proved to be unsuccessful. Rather, one of ordinary skill would more likely turn to a different drug class altogether, or an alternative treatment method, for patients deemed non-responsive to SSRIs.

Even if, *arguendo*, one of ordinary skill would have expected the treatment-resistant patient population to respond to a second SSRI, this is merely a broad generalization and would have provided no reasonable expectation of success with respect to the efficacy of escitalopram

in particular. Boegesoe does not cure this problem because one of ordinary skill in the art reading Boegesoe would understand that it generically discloses the use of escitalopram for the treatment of patients with depression, but provides no guidance as to whether or not this compound would be effective in SSRI-resistant patients being treated for PMS, as called for in the pending claims. A substantial percentage of patients do not respond to certain SSRIs. *See* specification at p. 1, lines 12-19. Hence, even if it might have been reasonably expected (albeit to a diminished degree) that a second SSRI would be effective in treating PMS in non-responsive patients, the disclosure in Boegesoe would not have provided the requisite motivation to single out escitalopram from the several other known SSRIs as the SSRI of choice.

The Examiner implies that all patients diagnosed with PMS also have a diagnosis of depression, and therefore, treating depression will necessarily treat patients with PMS. *See* Office Action, pages 5-6. Not all PMS patients, however, have depression. Depression is just one of many possible symptoms that patients with PMS might experience. Other possible symptoms include: affective lability, irritability, anger, tension, fatigue, malaise, loss of concentration, changes in appetite, food cravings, sleep disturbances, breast tenderness, swelling, headaches, joint or muscle pain, bloating, and weight gain (*see* Norden, col. 3, lines 5-16). One of ordinary skill in the art would not have been motivated or have had a reasonable expectation of success for treating PMS by treating only one possible symptom (i.e., depression). By analogy, one of ordinary skill in the art would also not have a reasonable expectation of success in treating cancer by treating depression (e.g., because it is only one possible symptom of cancer and is not necessarily present).

Finally, the cited references fail to suggest the desirability of using escitalopram to treat PMS in the specific patient population called for in these claims. *See* MPEP § 2143.01(I) (to establish obviousness, the prior art must suggest the desirability of the claimed invention). A person of ordinary skill in the art would not find it desirable to treat a patient with PMS who failed to respond to an SSRI (other than escitalopram) with another SSRI, because the patient would have been deemed an SSRI non-responder. At best, the references only provide general guidance and an invitation to experiment further with other SSRIs, which is insufficient to

establish obviousness. MPEP § 2145(X)(B); *In re Dow Chemical Co.*, 837 F.2d 469 (Fed. Cir. 1988); *see also Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361 (Fed. Cir. 2000) ("'obvious to try' is not the standard"); *In re Roemer*, 258 F.3d 1303 (Fed. Cir. 2001) (prior art that provides only general guidance does not establish obviousness).

In summary, claims 20-38 are not obvious because one of ordinary skill in the art would not have been motivated to use escitalopram to treat PMS in the treatment-resistant patient population called for in the present claims after a first member of this same class of drugs had proven unsuccessful, particularly because several other types of treatment options were known to those of skill in the art and would have therefore been more reasonably selected. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Conclusion

In view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining that the Examiner believes can be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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